

Applicant recognizes that different claims are entitled to different priority dates. This series of applications is based on ongoing research and some of the elements of claims 1-3, 11 and 12 were not discovered until the utility application was filed.

Claim objections. The Examiner has objected to claims 10, 13-15 and 17 under 37 CFR 1.75 as being in improper form. Claims 10 and 13-15 depend from claim 9. Claim 9 as amended is not a multiple dependent claim, therefore the objections to claims 10 and 13-15 should be removed. In order to clarify further that dependency is in the alternative, Applicant has deleted the "s" after claim in each of claims 10, 13-15 and 17.

Claim rejections under 35 USC § 112, the Examiner has rejected claims 4-9 as being indefinite because of the ambiguous wording of claim 4. Claim 4 has been amended to delete the confusing term "administering "to the subject." As now written, the claim distinctly claims a composition. Claim 11 as amended corrects the error of the unnamed Vitamin. Support for the insertion of Vitamin B₁₂ is found on page 18 line 3 of the specification.

Claim rejections under 35 USC § 102, The Examiner has rejected claims 4-7 and 9 under 35USC § 102 as being anticipated by Cotter et al. (USPN 4,920,098). Applicant respectfully asserts that Cotter does not anticipate the present invention as claimed in claims 4-7 and 9. Cotter discloses a complex supplement meant to correct the undernutrition sometimes, but not always, found in cardiac patients. The present invention is directed only to improvement of cardiac function and, lacking the nutrients of Cotter, is not claimed to have a benefit on undernutrition. Cotter does include eight grams per liter of ribose. However, Cotter does not provide instructions as to how much of the liquid supplement should be administered each day. Examiner is requested to note that a liter comprising four large glasses of fluid. Nothing in Cotter would suggest either that ribose rather than, for example, the protein or fatty acid components of the supplement, is responsible for improving the status of cardiac patients. Furthermore, since Cotter is directed at improving the nutritional status of those cardiac patients, those patients in acceptable nutritional status as to protein and fatty acids, would not have any

of the advantages of the ribose component of Cotter's supplement. In contrast, the Applicants have selected a low dosage (claim 6: two to ten grams of D-ribose; claim 7: three to eight grams of D-ribose) that has been found to be beneficial for improving cardiac and vascular function, without added protein or fatty acids.

Claim rejections under 35 USC§ 103. The Examiner has rejected claims 1-3, 9 and 16 under 35 USC § 103 (a) as being unpatentable over Cotter et al. (USPN 4,920,098) in view of Foker (USPN 4,719, 201). Cotter discloses a complex supplement comprising ribose. Nothing in Cotter suggests that ribose alone would benefit subjects with congestive heart failure. Foker does disclose that continuous intravenous infusion of ribose is beneficial in recovery from surgically induced global ischemia resulting in severely reduced ATP levels in a dog. The Examiner is requested to note that the dogs used in the Foker work were young, healthy dogs that were experimentally subjected to severe ischemia. Congestive heart failure and peripheral vascular disease in a clinical setting is generally caused by vascular disease, such as hypertension or atherosclerosis or ischemia (see specification page 3, lines 20-30). The patients are generally advanced in years. Because of their condition, they suffer from poor cardiac or peripheral circulation, but in general have not experienced the drastic decrease in cardiac ATP as seen in Foker.

Applicant submits that Foker would not teach or suggest that the ribose in the complex supplement of Cotter is responsible for the benefit sought. Foker infused about 17 grams of ribose per day into the 25-30 kilogram dogs. This amount is equivalent to about 40 grams for a 70 kilogram man. Furthermore, taking into account that the bioavailability of infused ribose is optimal, the dogs of Foker would achieve a much higher steady state level of ribose than the subjects of this invention who take intermittent, usually oral, doses of ribose. Examiner is also requested to take note that both the Cotter and Foker patents issued ten or more years before the present invention was discovered. During that time, despite the motivation of Cotter and Foker and the need for therapy to improve the status of cardiac patients (see specification page 3, lines 10-17), no one combined the teachings of these two patents and determined the exact low dosage and times of

administration to make this therapy available to the public (specification page 12, lines 23-30).

Claims 8, 11 and 12 are rejected under 35 USC § 103 (a) as being unpatentable under Cotter et al. in view of each of Foker and Wakat (USPN 6,054,128). Applicants assert that Wakat adds nothing to the teachings of Cotter and Foker. Wakat teaches a complex mixture of herbs and vitamins to promote a healthy cardiovascular system. It is well known and admitted by Applicant (see specification, page 4, lines 11-28) that cardiovascular patients may have suboptimal levels of some vitamins and amino acids and would derive some additional benefit from these additives, when combined with ribose. Several specific vitamins and amino acids plus glucose are suggested to have some benefit (see specification page 17, line 11 to page 18, line 9).

Applicant disagrees that it is obvious to take the compositions of this invention one to four times per day. Applicant has carefully titrated the dosage and administration protocol as reflected in Compositions A and B (page 17, lines 16-30; page 18, lines 1-6) and has clearly established that the preferred dose is five grams of ribose taken one to four times per day. Claims 5 and 11 have been amended to reflect the findings that higher doses are not required to obtain the benefit of this invention and may be accompanied by deleterious effects which would deter subject compliance (see specification page 12, line 23-30).

Applicant agrees with the Examiner that hypertension is often a predisposing factor for congestive heart failure following a myocardial infarction. However, the subject of Example 6 has not experienced a myocardial infarction and in fact has mild hypertension. She could be considered a healthy, normal person. None of the prior art would teach or suggest that mild hypertension would be relieved by administration of ribose.

Applicant submits that the claims being amended, they are now in proper form for allowance, which is earnestly requested.

Respectfully submitted,

By their representative,

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231 on this 22nd day of April, 2003.